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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,861	02/11/2000	CARLO RICCARDI	RICCARDI=1	7791

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WASHINGTON, DC 20004

EXAMINER
EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
1635	29

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/403,861	RICCARDI, CARLO	
	Examiner	Art Unit	
	Janet L. Epps-Ford, Ph.D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 41-48 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 3-19-03.

3. Claim 41, and those claims dependent thereon, were amended to recite a GILR protein encoded by the nucleotide sequence according to SEQ ID NO: 1 or by a nucleotide sequence capable of hybridizing with SEQ ID NO: 1, under hybridization conditions of 5X SSC, 5X Denhardt's solution, 1% SDS, 100 μl tRNA, and 20 mM sodium pyrophosphate (pH 6.8) at 42°C and under washing conditions of 0.2 X SSC, 0.1% SDS at 65°C, wherein said GILR protein is capable of inhibiting apoptosis and stimulating lymphocyte activity.

4. Applicant's arguments have been fully considered but are not persuasive. Applicants traverse the instant rejection by way of amending claim 41 to recite the hybridization and wash conditions as supported in the specification at the bottom of page 57. Moreover, Applicants state "[T]he disclosed highly stringent washing conditions (low ionic strength and high temperature) selects for only nucleotide sequences with high sequence homology/identity to SEQ ID NO: 1." However, contrary to Applicant's assertions, the current amendment to claim 41 does not properly reflect the hybridization conditions as set forth on the bottom of page 57, specifically

claim 41 as amended does not properly sets forth the concentration of the tRNA used in the hybridization solution. Claim 41 as amended recites wherein 100 μl tRNA, however the specification as filed recites 100 μg/μl tRNA in the hybridization solution described on the bottom of page 57. Moreover, Applicants have not amended claim 41 to recite the hybridization and wash times as set forth in the conditions described in the specification as filed. Furthermore, the conditions described in the specification do not indicate the type of stringency of hybridization, i.e. if the conditions are considered low, moderate, or highly stringent conditions. It is also noted that the conditions set forth in the specification resulted in the identification of fifty possible candidate nucleic acid sequences with apparent homology to the labeled murine GILR cDNA that served as a probe of the human lymphocyte cDNA library. After the first hybridization procedure, two more screens were required in order to identify the human cDNA clone, having 86% identity to the murine cDNA clone. The hybridization conditions set forth on the bottom of page 57, alone, were not sufficient to identify the human GILR cDNA sequence, further experimentation was required in order to reduce the number of identified clones down to a workable number of clones, see page 58, lines 1-7.

As stated in the prior Office Action, the specification as filed, page 25, lines 14-28, describe the DNA sequences encompassed by the claimed invention as capable of hybridizing with a cDNA sequence derived from the coding region of a native GILR protein, in which such hybridization is performed under moderately stringent conditions, and which encode a biologically active GILR protein." (It is first noted that the instant claims do not recite that the conditions for hybridization are "moderately stringent" as set forth in the specification as filed.) Moreover, the specification as filed states that "these hybridizable DNA sequences therefore

include DNA sequences which have a relatively high homology to the native GILR cDNA sequence and as such represent GILR-like sequences which may be for example, naturally-derived sequences encoding the various GILR isoforms, or naturally-occurring sequences encoding proteins belonging to a group of GILR-like sequences encoding a protein having the activity of GILR." Furthermore, these sequences also include, "for example, sequences encoding analogs, fragments and derivatives of GILR, all of which have the activity of GILR." (page 25, lines 14-28). Therefore, based upon the description of the claimed invention set forth in the specification as filed, the instantly claimed invention encompasses nucleic acid sequences "encoding analogs, fragments and derivatives of GILR, all of which have the activity of GILR."

However, the specification as filed does not clearly provide a structural description of the full scope of nucleic acid sequences that are encompassed by the claimed invention, particularly wherein the nucleic acid sequence is capable of hybridizing under stringent conditions to SEQ ID NO: 1. Moreover, the specification as filed does not provide a description of the recited "stringent conditions" for hybridization, wherein such conditions would produce nucleic acid molecules that would encode proteins according to the present invention. It is also noted that since the instant claims are not limited to any particular type of stringent conditions, i.e. low, moderate or high stringency, the instant claims broadly encompass nucleic acid sequences that are capable of hybridizing to SEQ ID NO: 1 under low, moderate, or highly stringent conditions, and that are capable of inhibiting apoptosis and stimulating lymphocyte activity.

Again, as stated previously, Applicant's specification does not sufficiently describe a clear nexus relationship between the amino acid structure of the GILR protein and the claimed functional limitations wherein the GILR protein is "capable of inhibiting apoptosis and

stimulating lymphocyte activity." Applicants have not provided any functional evidence that only the conserved regions between the human and mouse proteins are responsible for rendering the protein capable of inhibiting apoptosis and stimulating lymphocyte activity. The skilled artisan would have to resort to trial and error experimentation in order to identify those nucleic acid sequences that are capable of hybridizing to SEQ ID NO: 1 under stringent conditions, and further test the proteins encoded by those sequences for their ability to inhibit apoptosis and to stimulate lymphocyte activity. Moreover, it is noted that the instant claims are not limited to only those proteins or nucleic acid sequences that comprise the conserved regions that were identified between the human and mouse GILR sequences.

Additionally, Applicant's assert that one of skill in the art would clearly understand from Figure 15 that the preferential sites of amino acid residue changes would be where residues are not conserved between human and mouse GILR because these residues would be expected to be unimportant in determining GILR activity. Contrary to Applicant's assertions, it is noted that Applicant's are basing protein activity upon a consideration of the primary amino acid sequence structure; however, it is well known in the art that protein activity is a function of the overall tertiary structure of the folded protein. Apart from experimentation, one of skill in the art would not be able to predict the function of a mutated protein. Applicants have not provided any evidence in this regard.

Applicants have not provided a sufficient structural description of the claimed invention that would allow one of skill in the art to envision the full scope of the claimed invention. In order to isolate the claim invention the skilled artisan must isolate nucleic acid molecules that hybridize to SEQ ID NO: 1 using conditions that are not adequately supported in the

specification as filed, isolate the encoded polypeptide and test for its ability to inhibit apoptosis and stimulate lymphocyte activity. Nowhere in the written description guidelines does it provide for applicants to use a method of isolating a protein sequence and testing for the desired function, as a means for adequately describing an invention. The guidelines state that "[P]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention." In the instant case, other than the sequences that describe the mouse and human GILR proteins, one of skill in the art would not be able to immediately envision the structures of the full scope of compounds encompassed by the claimed genus without further experimentation.

The full scope of Applicant's claimed invention was not "ready for patenting" at the time of filing of the instant invention. Therefore applicants were not in possession of the full scope of the claimed GILR protein derivatives according to the present invention.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE

SEAN McGARRY
PRIMARY EXAMINER
1635